

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

Claim 7 has been revised to include the limitation of claim 8, which has been cancelled without prejudice. Claims 9 and 11 have been amended to depend from claim 7. That claims have been revised/cancelled should not be taken as an indication that Applicants agree with any view expressed by the Examiner. Rather, the revisions are made merely to advance prosecution and Applicants reserve the right to pursue any deleted subject matter in a continuation application. New claims 23-25 have been added. The new claims as presented find support throughout the application, including in claims 1, 10, 13 and 14 as originally filed and at page 27, line 30 to page 28, line 30.

Claims 7-22 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order in view of the above-noted claim revisions and for the reasons that follow.

The Examiner again contends that while the specification is enabling for preventing or treating *S. flexneri* with ST157 in cell culture, it does not reasonably provide enablement for treating any pathogen with any Abl tyrosine kinase inhibitor in humans. (The Examiner's acknowledgement of the novelty of a method of preventing or treating infection by *Shigella flexneri* with ST1571 is noted (see new claims 23-25).) The Examiner also contends that the terms "a pathogen" and "an inhibitor of Abl tyrosine kinase" render the claims non-enabled.

The Examiner's assertions are, first, unsupported and, secondly, are not applicable to all of the rejected claims. As regards the inapplicability to all the claims, the Examiner's attention is directed to the fact that claim 21, for example, requires that the inhibitor be ST1571 and the

infection be a bacterial infection, claim 22 further defines the infection as a *Shigella* infection.

The Examiner offers absolutely no explanation as to why the claims should be limited to *Shigella flexneri*.

As regards support for the rejection, it is submitted that the Examiner offers nothing by way of evidence to rebut the presumption enjoyed by Applicants that the invention can be practiced as claimed. All that is provided is an unsubstantiated opinion. Given that the Examiner has not met his burden, nothing should be required of Applicants. Nonetheless, the following remarks are offered in an effort to advance prosecution.

The studies provided in the instant application reveal a new role for Abl tyrosine kinase in pathogen infection. They demonstrate a requirement for Abl tyrosine kinase in the cellular uptake of a pathogen. While the invention is specifically exemplified using *Shigella* as the pathogen and the STI571 (Gleevec) (an FDA approved drug currently in use in treating chronic myeloid leukemia) as the Abl kinase inhibitor, Applicants teach in the application that the invention is applicable to other pathogens using other Abl kinase inhibitors.

In support of their position, Applicants made of record with the June 13, 2007 Amendment articles showing that inhibitors of the Abl kinases (Gleevec/ Imatinib), as well as dual Src/Abl kinase inhibitors, such as Dasatinib and AZD0530, dramatically inhibit dengue virus infection and block assembly and maturation of the virus. The studies described in the articles employ the cell-based assays. While Chu and Yang (PNAS 104:3520 (2007)) (of record) indicate that they have developed an "efficient high-throughput" "immunofluorescence image-based assay suitable for identification of small molecule inhibitors of dengue virus", the same assay was used by Applicants to assay for compound inhibitors (Gleevec) or proteins (Abl kinases) that are involved in *Shigella* infection. The Chu and Yang article relates to one more in

a growing list of pathogens that require Abl kinases for infection of mammalian cells, and that are amenable to treatment using Abl kinase inhibitors.

The Examiner appears to dismiss the evidence provided on the basis that the articles were published after the filing date of the present application. The Examiner states “[t]he references presented were available after the priority date of this application and so do not teach what was in the possession of the inventors at the time the invention was made”.

Bearing in mind that the rejection was based on lack of enablement, the articles were provided in order to demonstrate the sufficiency of the subject disclosure. The teachings of the articles support Applicants’ position that the invention can be practiced as claimed. Stated otherwise, Applicants teach in the application (and claim in the original claims) that inhibitors of Abl tyrosine kinase can be used to prevent or treat pathogen infection in a mammal. While the Example provided relates to *Shigella flexneri*, the application clearly discloses that the invention is not limited to *Shigella flexneri* (see page 14, lines 8-25). The evidence provided in the form of post-filing technical articles is entirely consistent with this disclosure.

In view of the above, the Examiner is respectfully requested to reconsider his position. It is believed that, having done so, he will find withdrawal of the rejection to be in order.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

PENDERGAST et al
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Respectfully submitted,

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